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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,626	06/05/2001	Johanna Jacoba Maria Meulenberg	4041.1US	9761

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EXAMINER	
WINKLER, ULRIKE	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/874,626	MEULENBERG ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,7,10,14-22,25 and 27-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,7,10,14-22,25 and 27-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed November 30, 2004 in response to the Office Action of November 16, 2004 is acknowledged and has been entered. Claims 5, 7, 10, 14-22, 25 and 27-31 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 102

The rejection of claims 7, 10, 20, 21, 22, 28, 29, 30 and 31 under 35 U.S.C. 102(b) as being anticipated by Wensvoort et al. (WO 92/21375) **is maintained** for reasons of record. Upon review of the amended claims, the following claims 7, 10, 20, 21, 22, 30 and 31 have been included in the instant rejection for the reasons set out below.

Applicants arguments are that the instant invention contributes over the prior art because the instant invention discovered that the 5' terminal 10 nucleotides (SEQ ID NO:18) are needed for the method steps of producing a virus using a transfection step that utilizes transfection into a non-permissive cell. It is important to point out that the instant claims are drawn to compositions and not methods. The Office recognizes that the primary contribution of the instant invention is the observation that transfection through a non-permissive cell line significantly improves particle production and recovery of virus from *in vitro* transcribed RNA. See specification pages 19-20. This method allows for improved manipulation of an RNA viral clone. Applicants' arguments and amendments are not found persuasive because the instant claims are drawn to a composition.

The claims are drawn to compositions and the compositions read on a host cell that is naturally infected by a virus. Limitations such as "full-length DNA copy" or "*in vitro* transcribed RNA copy" or "genetically modified," without recitation of what kind of modification, are considered process steps that do not affect the structure of the underlying nucleic acid. When examining compositions the product-by-process steps are not given weight because patentability is only determined by the structure of the composition. In this instance the claims are not adding unnatural coding sequences that must be included in the composition and the claims are not deleting sequences from the natural occurring virus therefore the claims include virus that has not been modified structurally and reads on virus as it can occur in nature. The art of molecular virology is such that knowledge of the RNA structure provides information about the DNA structure and vice versa, additionally knowledge of either RNA oer DNA structure provides knowledge of the complementary structure.

Applicants have amended the instant claims to include SEQ ID NO:18. SEQ ID NO: 18 is an inherent feature of the deposited virus of Wensvoort et al. By applicants own admission "The Ter Huurne strain pRRSV (or LV) (deposited at CNCM, Paris under accession number I-1102) was isolated in 1991 and was grown in primary alveolar macrophages or in CL2621 cells." See specification paragraph 0029. When a composition is old, it is not rendered patentable by the discovery of either a new characteristic or a new structure. "Artisans of ordinary skill may not recognize the inherent characteristic or functioning of the prior art.... Insufficient prior understanding of the inherent properties of a known composition does not defeat a finding of anticipation." See Atlas Powder Co. V. IRECO Inc., 190 F. 3d 1342, 51 USPQ 1943, 1947 (Fed. Cir. 1999). In this instance SEQ ID NO: 18 is an inherent feature of the virus deposited in the

WO 92/21375. "When the claimed compositions are not novel they are not rendered patentable by recitation of properties, whether or not these properties are shown or suggested in the prior art." In re Spada, 911 F.2d at 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990). The prior art of Wensvoort et al. discloses the viral strain Leystad virus (LV) (CDI-NL-2.91) which has been deposited at the Institute of Pasteur, Paris France with deposit number I-1102 under the Budapest Treaty. The claims 7, 10, 20, 21, 22, 28, 29, 30 and 31 read on a known strain and are therefore anticipated. Even if the prior references do not disclose the nucleotide sequences of the deposited strains, the nucleotide sequence of a viral strain is an inherent property of the viral strain. In this instance the "[t]he Ter Huurne strain pRRSV (or LV) (deposited at CNCM, Paris under accession number I-1102) was isolated in 1991 (Wensvoort et al.) and was grown in primary alveolar macrophages or in CL2621 cells." The 1991 isolate virus was sequenced by Wensvoort et al. in 1993 and the sequence was deposited in GenBank under accession number M96262 the same sequence was disclosed in the WO 92/21375 document. The sequence was later modified on 8 November 2000 GenBank under accession number M96262.2. The modification of the GenBank accession number provides further evidence that the prior isolated and deposited strain of I-1102 inherently possessed SEQ ID NO:18. Applicants may well have gone through the effort of determining the nucleotide sequence of the known strain and thereby have been able to determine the entire structure of the capped 5' end. The nucleotide sequence was an inherent property of the deposited strain at the time the invention was made and was therefore anticipated. The mere sequencing by applicants does not define a new composition, but an old composition with a property that was previously unknown but inherently present. Since the viral strain was deposited at the Institute of Pasteur, Paris France under the provision of

the Budapest Treaty, the strains were therefore apparently available to anyone skilled in the art who wished to acquire a sample and sequence the genome for themselves. An appropriate deposit can be relied on to meet both the enablement and description requirements of 35 U.S.C. § 112. See Ajinomoto Co. v. Archer-Daniels-Midland Co., 228 F3d 1338, 1345-1346, 56 USPQ2d 1332, 1337-1338 (Fed. Cir. 2000) ("The deposit of biological organism for public availability satisfies the enablement requirement for materials that are not amenable to written description."); Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 965, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002) ("[R]eference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of 35 U.S.C. § 112, paragraph 1.")

The process claim limitation such as "full-length DNA copy" or "*in vitro* transcribed RNA copy" or "genetically modified," without recitation of what kind of modification, are considered process steps that do not affect the structure of the underlying viral nucleic acid. When examining compositions the product-by-process steps are not given weight because patentability is only determined by the structure of the composition. In this instance the structure is inherently present in the prior art and therefore the claims are rejected.

Claim Rejections - 35 USC § 103

The rejection of claims 5, 7, 10, 14-22, 25, and 27-31 under 35 U.S.C. 103(a) as being unpatentable over Wensvoort et al. (WO 92/21375) in view of Moormann et al. (Journal of Virology 1996) **is maintained** for reasons of record, claims 29-31 have been added to the instant rejection as the amendments indicate that the RNA virus is a PRRSV virus. Upon review of the

instantly amended claims, the following claims 5 and 25 have been included in the instant rejection for the reasons set out below.

Applicants arguments are that the instant invention contributes over the prior art because the instant invention discovered that the 5' terminal 10 nucleotides (SEQ ID NO:18) are needed for the method steps of producing a virus using a transfection step that utilizes transfection into a non-permissive cell. It is important to point out that the instant claims are drawn to compositions and not methods. The Office recognizes that the primary contribution of the instant invention is the observation that transfection through a non-permissive cell line significantly improves particle production and recovery of virus from *in vitro* transcribed RNA. See specification pages 19-20. This method allows for improved manipulation of an RNA viral clone. Applicants' arguments and amendments are not found persuasive because the instant claims are drawn to a composition.

The response to Wensvort et al. has been discussed in the above 35 U.S.C. 102 rejection. Furthermore, the reference of Wensvort et al. also teaches that the LV virus could be used as a vector system and that sequences could be inserted in the corresponding proteins (see WO 92/21375, page 11, lines 13-19). The mere act of inserting a new sequence into an ORF indicates that there would be a deletion in an ORF. The instant claims as written do not require the deletion of an entire ORF, a deletion can be as little as a single nucleotide to meet the claim limitation of instant claims 5 and 25. The reference of Moormann et al. teaches *in vitro* transcribing cDNA from a positive stranded RNA virus to produce an infectious clone in the test tube. The reference also teaches replacing the ORF of one virus with the ORF of another strain of virus. Replacing these heterologous nucleic acid sequences produces a virus that can be used

as a vaccine, and this vaccine virus can be distinguished from a natural infection by the different antigens it presents. The reference does not teach making an infectious clone of PPRSV.

It remains the position of the office that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the cDNA taught by Wensvoort et al. and apply the *in vitro* method taught by Moorman et al. to produce an infectious RNA particle. One of ordinary skill in the art would have been motivated to use an *in vitro* transcribed virus, for the purpose of vaccination because the composition is completely defined. The artisan would know exactly what is in the composition that is being injected into the animal. One of ordinary skill in the art would have been motivated to produce a vaccine that contains heterologous sequences in order to have a marker that can distinguish vaccinated from naturally infected animals. There is a high expectation of success in producing a replication competent virus when exchanging coding sequences from closely related viruses. Therefore, the instant invention is obvious over Wensvoort et al. in view or Moormann et al.

The rejection of claims 5 and 25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of applicants amendment to the claim.

Conclusion

Claims 5, 7, 10, 14-22, 25 and 27-31 are rejected.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER 8/18/05